

FEB - 6 1997

K961498

510(k) Summary

Proprietary Name: Resch Fixation Screw

Common Name: Small Bone Screw System

Classification Name and Reference: 21 CFR 888.3030

Single/Multiple Component Metallic Bone Fixation
Appliances and Accessories

Proposed Regulatory Class: Class II

Device Product Code: OR(87) HRS

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The Resch Fixation Screw is a series of titanium alloy screws, commercially pure or TMZF alloy, available in a 2.7mm diameter and lengths of 10mm to 40mm. The Resch Fixation Screws are intended to be used for Fractures or Arthrodesis of Carpals and Metacarpals, Radial Head and Radial Styloid Fractures, Metatarsal Fractures and Osteotomies of the Forefoot, and Intra-articular arthrodesis in the wrist. The screws are available with or without washers(used to prevent the head of the screw from sinking into osteoporotic bone), and are cannulated, fully threaded, and self-tapping.

The substantial equivalence of the Resch Fixation Screw is based on an equivalence in design, materials, intended use, and operational principles to Synthes' 3.0mm & 3.5mm Cannulated Screw Systems, Alphatec's Mini Lag Screw System, and Howmedica's Alta Modular Small Bone Plating System and Cfx Intramedullary Rod and Screw System.